

## Message Text

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PAGE 01 STATE 193353  
ORIGIN HEW-06

INFO OCT-01 ARA-14 ISO-00 OES-09 EB-08 COME-00 /038 R

DRAFTED BY:DHEW/FDA/JRWEINROTH  
APPROVED BY:OES/ENP/EN:WJWALSHIII  
DHEW/PHS/OASH/OIH/MCKEFAUVER  
ARA/CAR:SURBER  
ARA/AND;;WSERGEANT

-----045205 021154Z /45 53

P 011400Z AUG 78  
FM SECSTATE WASHDC  
TO AMEMBASSY KINGSTON PRIORITY  
AMEMBASSY CARACAS PRIORITY

UNCLAS STATE 193353

CORRECTED COPY (MRN 193353 VICE 193362)

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, JM, VE

SUBJECT: FDA INITIATED RECALL - NO EFFECTIVE NEW ANIMAL  
DRUG APPLICATION RECALL V-129-8

1. FDA ADVISES OF THE FOLLOWING RECALL:  
PRODUCT INVOLVED: ADRENAL CORTEX INJECTION, 10 AND 30 CC  
VIALS, A PRESCRIPTION DRUG REPORTEDLY LABELED FOR VETERIN-  
ARY USE ONLY.

2. PRODUCT IDENTIFICATION- PRODUCT IS UNDER ZIRIN  
LABORATORIES INTERNATIONAL INC., HIALEAH, FLA. LABEL. 10  
CC AND 30 CC VIALS OF ADRENAL CORTEX INJECTION, LABELED  
FOR VETERINARY USE. ZIRIN LABORATORIES IS AN OWN LABEL  
DISTRIBUTOR OF THIS PRODUCT. ALL LOTS ARE INVOLVED.

UNCLASSIFIED

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PAGE 02 STATE 193353

3. MANUFACTURER/RECALLING FIRM: ANTHONY PRODUCTS, EL MONTE  
CA. DISTRIBUTOR/RECALLING FIRM: ZIRIN LABORATORIES  
INTERNATIONAL INC., 199 W. 24TH STREET, HIALEAH, FLA. 33010.

4. REASON FOR RECALL RECOMMENDATION: FIRM CONDUCTED A  
RECALL IN U.S. AS A RESULT OF FDA REGULATORY LETTER DATED  
1/9/78 STATING THE PRODUCT IS CONSIDERED TO BE A NEW DRUG

WITHOUT AN APPROVED NEW ANIMAL DRUG APPLICATION.

5. NO DEATHS OR INJURIES HAVE BEEN REPORTED. THE FIRM DID NOT RECALL FROM THE FOREIGN CONSIGNEES, STATING THAT PREVIOUS EXPERIENCE HAS SHOWN THAT THE FOREIGN ACCOUNTS WILL NOT RETURN THE PRODUCT.

6. THE FIRM CONTINUED TO EXPORT THE PRODUCT AFTER FDA ADVISED THEM THAT IT WAS ILLEGAL BY A SECOND LETTER DATED 2/15/78.

7. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO ADVISE THEM OF RECALL. POST IS TO INFORM CONSIGNEES THEY ARE TO CONTACT ZIRIN LABORATORIES INTERNATIONAL REGARDING DISPOSITION OF PRODUCT AND FOR ANSWERS TO ANY QUESTIONS THEY MAY HAVE.

8. FOREIGN CONSIGNEES AS FOLLOWS:

N. BAILEY, 16 GENGIC AVE., KINGSTON JAMAICA

D. STENNENT, 25 SANDY LANE, KINGSTON, JAMAICA

MS. LILIAN ROJAS, CALLE HUMOCARO QTZ CURADRE, EL MARAUEZ, ESTADO MIRANDO, CARACAS, VENEZULA

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PAGE 03 STATE 193353

DENNIS SASSO, 8 EARLS COURT, 9 CORRIEME CRESCENT, 28 CALSTON DRIVE, KINGSTON, JAMAICA

BURKE, KINGSTON JAMAICA

RUDOLPH EDWARD, 16 CROSS ROADS, KINGSTON, JAMAICA

REN GONZALES, 46 EVELYN CRESCENT, KINGSTON JAMAICA

L. HYE, 2 G HIGHLAND DRIVE, KINGSTON, JAMAICA VANCE.  
VANCE

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 jan 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** ANIMALS, DRUGS, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 01 aug 1978  
**Decaption Date:** 01 jan 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 jan 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1978STATE193353  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/JRWEINROTH  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D780316-0120  
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**Message ID:** d81d6b59-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
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**Previous Handling Restrictions:** n/a  
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**Retention:** 0  
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**Review Content Flags:**  
**Review Date:** 29 mar 2005  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** N/A  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 1575962  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA INITIATED RECALL - NO EFFECTIVE NEW ANIMAL DRUG APPLICATION RECALL V-129-8  
**TAGS:** OGEN, ETRD, EIND, TBIO, JM, VE  
**To:** KINGSTON CARACAS  
**Type:** TE  
**vdkgvwkey:** odb://SAS/SAS.dbo.SAS\_Docs/d81d6b59-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Sheryl P. Walter  
Declassified/Released  
US Department of State  
EO Systematic Review  
20 Mar 2014  
**Markings:** Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014